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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,105	09/26/2000	Maurice Moncany	2356.0062-05	5805

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EXAMINER
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WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/670,105

Applicant(s)

MONCANY ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 27-48 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 27, 28, 32, 33, 38, 39, 43, 44, drawn to a polypeptide obtained by the amplification of a DNA sequence and expression in a host cell, classified in class 435, subclass 91.2.
- II. Claims 29, 31, 40, 42, drawn to an antibody directed against the polypeptide, classified in class 530, subclass 389.1.
- III. Claims 30, 41, drawn to a method of using the antibody for viral detection, classified in class 435, subclass 7.1.
- IV. Claims 34-37, 45-48, drawn to a polynucleotide, classified in class 536, subclass 23.72.

For each invention of groups I-III above, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects one of the inventions of groups I-III, election to a single combination resulting in one invention is also required. Applicant is required to select a single forward primer (A-H), a single reverse primer (I-M) to be used in the amplification of the sequence. Applicant is also required to elect a single viral strain (N-R) as the sequences between the viral strains differ resulting in a structurally different polypeptide amplified nucleotides encoding structurally different polypeptides.

**Forward Primer:**

- (A). SEQ ID No: 68.
- (B). SEQ ID No: 46.
- (C). SEQ ID No: 48.
- (D). SEQ ID No: 49.
- (E). SEQ ID No: 52.

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- (F). SEQ ID No: 53.
- (G). SEQ ID No: 55.
- (H). SEQ ID No: 56.

Reverse Primer:

- (I). SEQ ID No: 47.
- (J). SEQ ID No: 50.
- (K). SEQ ID No: 51.
- (L). SEQ ID No: 54.
- (M). SEQ ID No: 57.

Viral strain

- (N). SIV.
- (O). HIV-1 Bru.
- (P). HIV-1 Mal.
- (Q). HIV-1 Eli.
- (R). HIV-2.

For the invention of group IV above, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects the invention of group VI, election to a single polynucleotide is required. The claims are directed to purified polynucleotides and provide a list of sequences, there are no amplification steps using the polynucleotides hence the restriction is limited to a single disclosed polynucleotide sequence. Applicant is also required to elect a single sequence (S-AE).

- (S). SEQ ID No: 68.
- (T). SEQ ID No: 46.
- (U). SEQ ID No: 48.
- (V). SEQ ID No: 49.
- (W). SEQ ID No: 52.
- (X). SEQ ID No: 53.
- (Y). SEQ ID No: 55.
- (Z). SEQ ID No: 56.
- (AA). SEQ ID No: 47.
- (AB). SEQ ID No: 50.
- (AC). SEQ ID No: 51.
- (AD). SEQ ID No: 54.
- (AE). SEQ ID No: 57.

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The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(H) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent structurally different polynucleotides. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

Inventions (J)-(M) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent structurally different polynucleotides. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

Inventions (N)-(R) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides. Therefore, where structural identity is required, such as for the production of antibodies, the different sequences have different effects.

The proteins of group I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions represent structurally different polypeptides. Therefore, where structural identity is required, for the production of antibodies the different structures represent different epitopes and will have different effects.

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Inventions (S)-(AE) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent structurally different polynucleotides. Therefore, where structural identity is required, such as for hybridization or expression or activity, the different sequences have different effects.

The polynucleotides of group IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization, the different sequences have different effects.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case PCR can be used in order to detect the presence of virus, which is a materially different process. The antibody product can be used for affinity purification of the virus, which is also a materially different process..

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Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, the literature and sequence searches required for each of the groups are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Ulrike Winkler, Ph.D. 9/5/02